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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,448	06/04/2001	Patrick Midoux	USB98ASIDM	3117

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EXAMINER

SCHNIZER, RICHARD A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 12/30/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,448

Applicant(s)

Midoux

Examiner

Richard Schnizer

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 24, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above, claim(s) 15, 16, and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☒ Claim(s) 5-14, 17, and 19 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Jun 4, 2001 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(a). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1 6) ☐ Other:

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DETAILED ACTION

An amendment was received and entered as Paper No. 8 on 10/24/02.

Claims 1-19 are pending in the application.

Applicant's election with traverse of group IV, claims 9, 10, 17, and 19, directed to a composition comprising an oligomeric conjugate and an oligonucleotide, is acknowledged. Traversal is on the grounds that the prior art relied upon by the Office was not unity-destroying because it did not anticipate claim 1. The Office concedes that Applicant is correct and regrets the error. Nonetheless the claimed inventions lack unity of invention because 37 CFR 1.475 does not allow for claims to more than one composition, or for more than a first method of use. In this case group I is drawn to a composition consisting of an oligomeric conjugate, groups II-V are drawn to compositions comprising the combination of an oligomeric conjugate and various structurally and functionally distinct agents, and groups VI-XVIII are drawn to various methods of using the foregoing compositions. For these reasons, the restriction requirement is deemed proper and is made FINAL. However, after further consideration, the Office agrees to Applicant's request to rejoin claims 11-14 with the elected group, wherein claims 11-14 correspond to a first method of use of the claimed composition. Furthermore, in order to examine the claimed invention, it is necessary to rejoin claims 1-8. Accordingly the elected group is considered to consist of claims 1-14, 17, and 19, drawn to compositions comprising an oligomeric conjugate and an oligonucleotide, and a first method of using the composition.

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Claims 15, 16, and 18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Claim Objections

Claims 5-14, 17 and 19 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiply dependent claim. See MPEP § 608.01(n). Accordingly, the claims 5-14, 17 and 19 have not been further treated on the merits. Applicant is advised that new claims written in proper format which recapture the subject matter of claims 5-14, 17 and 19 will be considered only to the extent that they are defined by the elected group.

Claims 1-4 are objected to for the following reasons:

- A. All sentences beginning with a singular noun should be amended to begin with an article.
- B. The use of arrows and dashes to denote portions of claims is highly irregular, the substitution of letters or numbers for arrows and dashes is recommended.
- C. In paragraph 4 of claim 1, “posses” is misspelled;
- D. In paragraph 8, either “residues” should be singular, or the word “an” prior to “uncharged” should be deleted. Also “oligomeric” is misspelled (should be “oligomer”).

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E. Claims should employ active rather than passive voice. For example, in claim 1, the phrase “said oligo being as follows” should be replaced with “wherein said oligomer further comprises”, followed by a positive statement of what the characteristics the oligomer may or may not have. As a further examples, “present the additional properties” in claim 2 should be replaced with “further comprise”, followed by a positive statement of the characteristics of the invention, and “are” in line 2 of claim 4 should be replaced with “consist of”.

F. The English spellings of “quinolins”, “pterins”, and “pyridins” should be used.

G. If the Examiner understands claim 2 correctly, the entire second paragraph, as well as the phrase “present the additional properties” (objected to above), could be replaced with “have a pKa in aqueous medium of greater than 7.0 and less than 7.4”, thereby simultaneously simplifying and clarifying the claim.

In summary, in an application for a US Patent, Applicant should attempt to write the claims to conform with US practice, i.e. use English grammar and spelling where possible, and employ active rather than passive voice.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4 are indefinite because:

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation "at least 50%", and the claim also recites "advantageously 60% to 95%, particularly 80% to 90%" which are narrower statements of the range/limitation. Further, claim 4 recites the broad recitation "from 1 to 10", and also recites "particularly from 2 to 6" which is a narrower statement of the range/limitation.

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Regarding claims 1-4, the terms advantageously and particularly render the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

It is unclear if the claim requires substitution of free -NH_3^+ residues with protonable residues, wherein the substitution occurs in a weak acid medium, or whether the claim requires substitution of NH_3^+ residues with residues that are protonable in a weak acid medium.

The phrase “leading in such a weak acid medium to a destabilization of cellular membranes” is confusing. It is unclear how the formation of a conjugate can lead to destabilization of cell membranes. The claim recites no steps in which the composition is brought into contact with any membranes. The claims are also indefinite because they appear to require destabilization of cellular membranes, but recite no steps under which this process is carried out.

The meaning of the term “correspond” is unclear in the phrase “they do not correspond to a recognition signal.” In what ways may entities “not correspond”? Do entities which share several identical atoms “correspond”? The metes and bounds of the claim are unclear because it is unknown how “correspond” is intended to limit the claim.

The use of the word “either” in paragraphs 10-12 of claim 1 is confusing because it is ungrammatical. It is not clear if the limitations that follow are recited as alternatives or not.

The claims recite “the cellular membrane” without antecedent basis.

Claims 3 and 4 are indefinite because it is not clear if they require the protonable residues to:

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a) belong simultaneously to the chemical groups quinolines, pterins, and pyridines,

or

b) comprise an imidazole ring and belong to one of the chemical groups,

alternatively: quinolines, **or** pterines, **or** pyridines, or

c) belong to one of the chemical groups alternatively: imidazoles, **or** quinolines, **or** pterines, **or** pyridines.

Because the claims are so indefinite, no meaningful search of the prior art could be conducted.

Summary

Claims 5-14, 17 and 19 are objected to as being improperly multiply dependent and were not further treated on the merits.

Claims 1-4 are indefinite.

Claims 1-4 are free of the prior art of record.

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Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014. Additionally correspondence can be transmitted to the following RIGHTFAX numbers: 703-872-9306 for correspondence before final rejection, and 703-872-9307 for correspondence after final rejection.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.

Richard Schnizer, Ph.D.

Jeffrey Siew
JEFFREY SIEW
PRIMARY EXAMINER
12/23/02